

RS



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/744,675

01/29/2001

Edward L. Squires

XY-EQUINE3-U

3456

33549

7590

04/08/2005

SANTANGELO LAW OFFICES, P.C.
125 SOUTH HOWES, THIRD FLOOR
FORT COLLINS, CO 80521

EXAMINER

MYERS, CARLA J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,675

Applicant(s)

SQUIRES ET AL.

Examiner

Carla Myers

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-51 and 136-145 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-51 and 136-145 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the amendment filed January 13, 2005. Claims 45-51 and 136-145 are pending. Applicant's arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All objections/ rejections not reiterated herein are hereby withdrawn. This action is made final.

Applicants response requests an opportunity for an interview "in the event questions remain." It is noted that Applicant's representative contacted the Examiner on February 16, 2005 to request an interview for February 18, 2005. The Examiner was not available for an interview on that date. Applicants did not contact the Office to schedule an interview at a later time. Further, it is noted that it is not the Office's policy to place the responsibility upon the examiner to schedule an interview if, upon review of a response, an application is not found to be allowable.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

Art Unit: 1634

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 45-47 and 49-51, 136-140, and 142-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rens (U.S. Patent No. 5,985,216) in view of Wilhelm (Cryobiology (1996) 33:320-329) and further in view of Rath (Theriogenology. April 1997, 795-800; cited in the IDS) .

Rens teaches a method of high speed flow cytometry for sorting sperm. In the method of Rens (see columns 4-6), a sample of sperm is obtained from a male mammal, the sperm is stained with Hoeschst 33342 dye in order to distinguish between viable and nonviable sperm (column 5, lines 4-10), the sperm are sorted in a high speed flow cytometer using a nozzle that forms a stable droplet containing each individual sperm cell (column 2, lines 23-32), the sperm are sorted according to their sex characteristics and isolated populations of X- and Y-chromosome bearing sperm are collected. Approximately 50% of the sperm were viable and the sorting was performed at sampling rates of 500 sperm/sec and 2000 sperm/sec (see column 6). Further, the nozzle allowed for sample rates up to at least 15,000 sperm/sec (column 4, lines 29-31). Rens exemplifies using the claimed sorting method using rabbit, bull, mouse and human sperm (columns 4-7) and states that the sorting method can be used with any

mammalian sperm (column 4, lines 38-42). Rens does not specifically exemplify applying the sorting method to equine sperm.

However, Wilhelm teaches the use of equine sperm for the purpose of artificial insemination. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the method of Rens to the sorting of equine sperm in order to have provided an effective means for distinguishing between and collecting populations of X- and Y-chromosome bearing sperm useful for artificially inseminating equine.

Secondly, Rens does not specify the solution into which the sperm cells are collected and thereby does not teach collecting the sorted sperm in a skim milk solution. However, Rath (page 796) teaches collecting sex-sorted sperm into a collection media composed of TEST extender containing 2% hen egg yolk. Thus, Rath teaches the concept of collecting sperm sorted cells into a sperm extender medium. Wilhelm teaches extending equine sperm in skim milk solution containing 2% egg yolk by volume (page 322; referred to therein as SMEY). Wilhelm teaches that SMEY extender effectively preserves equine sperm during freezing and thawing and teaches that egg yolk and skim milk may contain components which protect spermatozoa membranes (page 326).

Accordingly, in view of the teachings of Rath and Wilhelm, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of Rens so as to have collected the equine sperm in the SMEY extender solution of skim milk and egg yolk in order to have sorted the sperm

Art Unit: 1634

into a medium that helped to preserve the sperm and/or which could be used for subsequently freezing and then thawing the sorted equine sperm. Specifically, Rath teaches that the sorted sperm are collected into a tube containing sperm extender and it would have been obvious to the ordinary artisan that alternative extenders that were known in art to be effective for preserving equine sperm, such as the skim milk extender of Wilhelm, could be present in the collection tube in order to ensure the proper collection of the sperm.

With respect to claims 47 and 140, the recitation of "about four percent egg yolk" is considered to encompass 2% egg yolk. Furthermore, it would have been well within the skill of the art at the time the invention was made to have modified the concentration of egg yolk in the extender solution in order to have provided the most effective concentration of egg yolk depending on the other reagents present in the extender solution.

With respect to claims 51 and 143, Rens does not specify the pressure used to operate the high speed cell sorter. However, methods for sorting equine sperm using high speed cell sorters were well known in the art at the time the invention was made. To determine the optimum conditions for performing a method step is well within the skill of the art. As discussed in MPEP 2144.05(b), "(w)here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

With respect to claims 136, 137, 144 and 145, Rens teaches that 4 to 5 million sorted sperm were used to inseminate dairy cows, but does not teach the quantity and volume of sperm in equine artificial insemination samples. Additionally, Rath (page 796) teaches the use of .2 million sorted porcine spermatozoa per oviduct and teaches resuspending sorted porcine sperm in a solution having a volume of .2 ml. Rath teaches that approximately 3.5 to 4×10^5 sperm cells were sorted into each tube. Since the parameters which effect artificial insemination of equine were known in the art at the time the invention was made, it would have been obvious to one of ordinary skill in the art and well within the skill of the art to have selected an optimum quantity of sperm, wherein said quantity would be less than 25 million and to have selected the optimum volume for the artificial insemination sample, so as to have provided the most effective sample for inseminating equine while keeping the number of sperm to be used for insemination at the lowest possible number given the constraints on how many sperm could be sorted per day and the cost of sorting. Additionally, the ordinary artisan would have recognized that the quantity of sperm and the volume of the sperm sample could be modified in order to have provided the most appropriate sperm sample depending on how the sample would be used – i.e., depending on the amount of sperm present in the original sample, whether the samples would be frozen prior to use, the number of samples to be used for insemination, and the type of insemination technique. Accordingly, to have generated sorted sperm samples containing less than 5 or 25 million sperm or to have generated sorted sperm samples in a volume of .2 or 1 ml would have been obvious to one of ordinary skill in the art because the ordinary artisan

Art Unit: 1634

would have recognized that the quantity of sperm and the volume of sample should be varied depending on how the sperm sample was to be further processed and / or used.

RESPONSE TO ARGUMENTS:

In the response of January 13, 2005, Applicants traversed the rejection over Rens in view of Wilhelm and Rath by arguing that Rens does not specifically exemplify applying the sorting method to equine sperm. However, the test of obviousness under 35 U.S.C. 103 is not express suggestion of the claimed invention in any or all of the references but what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them (In re Rosselet, 146 USPQ 183(CCPA 1965)). Accordingly, there is no requirement for Rens to exemplify a method of sorting equine sperm. The references, when taken collectively, would have lead one of ordinary skill in the art to the claimed method in which the sorting process of Rens was applied to equine sperm.

Applicants argue that Wilhelm teaches using a skim milk solution as an extender for freezing and thawing sorted sperm, but does not teach collecting the sorted sperm into a skim milk solution. It is stated that the teachings of the reference are different from those of the present claims and that the references do not suggest using the skim milk solution as a collection fluid. Applicants assert that neither Wilhelm nor Rath teach that the skim milk solution can be used to minimize stresses upon cells and provide for an easier reception. These arguments have been fully considered but are not persuasive. While Rens does not specifically discuss a collection fluid that is used to collect sorted equine sperm, Rath does teach that sorted sperm should be deposited

Art Unit: 1634

into a tube that contains an extender. Thereby Rath does disclose the importance of collecting the sperm in a tube that contains an extender. Rath exemplifies collecting porcine sorted sperm in a TEST-egg yolk extender solution. The ordinary artisan would have recognized that alternative extender solutions could also be used to collect the sorted sperm, particularly as dependent on the type of sperm that is being sorted and collected. Wilhelm teaches such an extender solution for use with equine sperm. Specifically, Wilhelm teaches using SMEY, which contains skim milk and egg yolk, as an extender for equine sperm and teaches that the SMEY solution provides an effective fluid for protecting equine sperm. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have collected the sorted sperm in the SMEY solution of Wilhelm because this would have provided an effective medium for protecting the equine sorted sperm and would have provided a medium that could be used for subsequent freezing of the sperm. Applicants arguments are directed to the individual references and the fact that the references taken individually do not teach the claimed invention. However, as discussed above, the test of obviousness is not what the references teach separately, but what the references taken collectively would have suggested to those of ordinary skill in the art presumed to be familiar with them. In the present case, the teachings of Rath of collecting the sperm in a tube containing extender and the teachings of Wilhelm of the effectiveness of the SMEY solution for equine sperm, would have suggested to one of ordinary skill in the art to have used the SMEY solution of Wilhelm for the extender in the collection tube. While Applicants teach advantages for using SMEY as a collection fluid and these particular

Art Unit: 1634

advantages may not be specifically recited in the cited references, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The motivation to combine references need not be the same as those disclosed by Applicants. Accordingly, it is maintained that the references when taken collectively would have suggested the claimed invention since Rath teaches collecting sperm in a collection tube that contains extender and Wilhelm teaches that SMEY is an effective extender for equine sperm.

Applicants argue that they disagree with the interpretation that "about 4% egg yolk" encompasses "about 2% egg yolk." However, Applicants do not provide a definition in the specification for what is considered to be encompassed by "about" and there is no art fixed definition for what constitutes "about." There are no limitations in the claims or teachings in the specification which would suggest to one of ordinary skill in the art that "about 4%" excludes 2%. Does "about 4%" egg yolk include only 4% egg yolk, or does it also include 3.9% or 3.5% or 3.0% etc egg yolk? Applicants further assert that this quantity of egg yolk would not have been obvious. However, to determine the optimum conditions for performing a method step is well within the skill of the art. As discussed in MPEP2144.05(b), "(w)here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). Further, Applicants have not established any improved or unexpected

Art Unit: 1634

results obtained using "about 4% egg yolk" in place of 2% egg yolk and thereby have not shown the criticality of using collection solutions containing this range of egg yolk concentrations. Nor have Applicants established that it would not have been within the skill of the ordinary artisan or obvious to the ordinary artisan to have selected this amount of egg yolk.

Applicants state that it is not a matter of routine experimentation to obtain the workable ranges for the pressure of the flow cytometer. It is asserted that higher pressures may cause damage to the sperm or could possibly kill the sorted sperm. It is also stated that "the fact that the present invention allows a flow cytometer to be operated at 50 psi and still establish separated sperm cells capable of successful fertilization may be an unexpected result." This statement is vague and is not supported by any factual evidence to support the contention of unexpected results or the use of pressures above those used in the prior art. As discussed previously, Applicants have not shown improved and unexpected results under all conditions, using any type of separation device, at pressures of "about" 50 psi and at all pressures above 50 psi. Nor have applicants shown improved and unexpected results under all conditions and using any type of separation device at sort rates at 900 viable sorted equine sperm cells per second and at all sort rates above 900 viable sorted sperm cells per second. What sorting rates are encompassed by "about 50 psi?" If this limitation is intended to distinguish the claims over the prior art, then it is important for Applicants to clarify the record and to provide a clear teaching as to the range of pressures encompassed by "at least about fifty pounds per square inch." Further, while Rens does not specify the psi

Art Unit: 1634

used for sorting, Rens does teach that approximately 50% of the sperm were viable and the sorting was performed at sampling rates of 500 sperm/sec and 2000 sperm/sec (see column 6) and that the nozzle allowed for sample rates up to at least 15,000 sperm/sec (column 4, lines 29-31). At the time the invention was made, it was well known in the art that the pressure and rates of sorting effect sperm viability. Thereby, the ordinary artisan would have been taken these facts into consideration when selecting the pressure and rates of sampling. It is noted that Applicants state that "affidavit support is available to further discuss and augment the foregoing comments." However, such an affidavit has not been submitted to the Office.

Applicants argue that the combination of references does not provide a reasonable expectation of success. It is asserted that with respect to Rens and Rath, "the flow cytometer is used to separate bovine and porcine sperm. However, the application of flow cytometry to equine sperm poses an additional problem – the fact that flow cytometers are not fast enough to sort the 250 million sperm typically required to successfully perform equine insemination while maintaining sperm viability." This argument has been fully considered but is not persuasive because it is not supported by any factual evidence. Further, if the known flow cytometers conventionally used in the art cannot be used with the present invention, then what flow cytometer may be used? The claims are not limited to any particular flow cytometer and the specification does not teach any particular flow cytometer. Applicants appear to be arguing that the conventional flow cytometers, and particularly the high speed flow cytometer of Rens, cannot be used to accomplish the claimed invention. Yet, Applicants have not taught an

Art Unit: 1634

alternative flow cytometer which could be used to accomplish the claimed invention and the claims are not limited to flow cytometers which provide for the asserted unexpected results.

3. Claims 48 and 141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rens in view of Wilhelm and Rath and further in view of Catt (cited in the IDS of January 29, 2001).

The teachings of Rens, Wilhelm and Rath are presented above. The combined references do not teach establishing a sheath fluid which contains a HEPES buffered medium. Catt teaches that semen may be diluted in a HEPES-buffered SOF (synthetic oviduct fluid) medium and that such a fluid is suitable for maintaining the viability of spermatozoa (see, e.g., page 252 and 257). Catt also teaches that it is beneficial to sort into a medium containing a cushioning of seminal plasma to increase the viability and motility of sperm. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of Rens in view of Wilhelm so as to have used a HEPES-buffered medium for establishing a sheath fluid because Catt teaches that this is a suitable dilution medium for sperm and thereby using HEPES-buffered medium as the sheath fluid would have achieved the benefit of ensuring the viability and motility of the sperm.

RESPONSE TO ARGUMENTS:

In the response, Applicants traversed the rejection by arguing that only the present invention recognizes the advantage of using HEPES-buffered medium as a sheath fluid for equine applications. However, Catt teaches that HEPES-buffered SOF

helps to maintain the viability of spermatozoa. The ordinary artisan would have recognized that the teachings of Catt were applicable to other types of sperm, including equine. While the HEPES- buffered SOF was developed for bovine sperm, this does not lead to the conclusion that the solution can be used only for bovine sperm. It is maintained that the ordinary artisan, recognizing that the HEPES-buffered SOF provided a protective solution for the sperm, would have been motivated to have used this solution as a carrier for the sperm in order to have maintained the viability of the sorted equine sperm.

4. Claims 45-51 and 136-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel (U.S. Patent No. 6,149,867) in view of Wilhelm (Cryobiology (1996) 33:320-329) and further in view of Rath.

It is noted that the '867 patent and the present application share a common inventor and assignee. However, the inventorship and assignee of the '867 patent is distinct from that of the present application.

Seidel teaches a method of high speed flow cytometry for sorting equine sperm. The method of Seidel comprises obtaining a sample of sperm from a male mammal, staining the sperm in order to distinguish between viable and nonviable sperm, sorting the sperm using a high speed flow cytometer having a nozzle that forms a stable droplet containing each individual sperm cell wherein the sperm are sorted according to their sex characteristics and isolating populations of X- and Y-chromosome bearing sperm are collected (see column 6). Seidel (column 7) teaches sorting at rates of greater than 500 sorts per second and up to 1000 to 1200 sorts per second. The reference also

Art Unit: 1634

teaches operating the flow cytometer at pressures of about 50 lbs per square inch (column 7). Seidel teaches that when sorting equine sperm, the preferred sheath fluid contains HEPES buffer (column 9).

Seidel teaches that "it has been known to place an initial collector fluid (17) in the bottom of the container to collect the cells so that they do not hit the bottom of the container" (column 10). Seidel states that the collector fluid "may serve to minimize chemical stresses upon the cells. In one regard, since it may be important to provide a nutrient to the cells both before and after sorting, the collector fluid (17) may be selected so as to provide a coordinated level of nutrient so that the levels are balanced both before and after sorting" (column 10). The reference teaches that an egg yolk solution may be used as the collection fluid and that the collection fluid may be chosen so that it is similar to the starting fluid environment or any other fluid environment used in the method (column 11). It is also stated that that the levels of egg yolk may be varied "as those skilled in the art readily understand" (column 11).

Seidel does not specifically teach using a collection fluid that contains skim milk. However, Rath (page 796) teaches collecting sex-sorted sperm into a collection media composed of TEST extender containing 2% hen egg yolk. Thus, Rath teaches the concept of collecting sperm sorted cells into a sperm extender medium. Wilhelm teaches extending equine sperm in skim milk solution containing 2% egg yolk by volume (page 322; referred to therein as SMEY). Wilhelm teaches that SMEY extender effectively preserves equine sperm during freezing and thawing and teaches that egg

Art Unit: 1634

yolk and skim milk may contain components which protect spermatozoa membranes (page 326).

Accordingly, in view of the teachings of Rath and Wilhelm, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Seidel so as to have collected the equine sperm in the SMEY extender solution of skim milk and egg yolk in order to have sorted the sperm into a medium that helped to preserve the sperm and/or which could be used for subsequently freezing and then thawing the sorted equine sperm. Specifically, Rath teaches that the sorted sperm are collected into a tube containing sperm extender and it would have been obvious to the ordinary artisan that alternative extenders that were known in art to be effective for preserving equine sperm, such as the skim milk extender of Wilhelm, could be present in the collection tube in order to ensure the proper collection of the sperm.

With respect to claims 47 and 140, the recitation of "about four percent egg yolk" is considered to encompass 2% egg yolk. Furthermore, as taught by Seidel, it would have been well within the skill of the art at the time the invention was made to have modified the concentration of egg yolk in the extender solution in order to have provided the most effective concentration of egg yolk depending on the other reagents present in the extender solution.

With respect to claims 136, 137, 144 and 145, Seidel (column 12) teaches using a low dose of sperm for artificial insemination and teaches concentrating bovine sperm to a level of 3-5 million sperm cells per ml (column 13), but does not teach the quantity

Art Unit: 1634

and volume of sperm in an equine artificial insemination sample. Additionally, Rath (page 796) teaches the use of .2 million sorted porcine spermatozoa per oviduct and teaches resuspending sorted porcine sperm in a solution having a volume of .2 ml. Rath teaches that approximately 3.5 to 4×10^5 sperm cells were sorted into each tube. Since the parameters which effect artificial insemination of equine were known in the art at the time the invention was made, it would have been obvious to one of ordinary skill in the art and well within the skill of the art to have selected an optimum quantity of sperm, wherein said quantity would be less than 25 million and to have selected the optimum volume for the artificial insemination sample, so as to have provided the most effective sample for inseminating equine while keeping the number of sperm to be used for insemination at the lowest possible number given the constraints on how many sperm could be sorted per day and the cost of sorting. Additionally, the ordinary artisan would have recognized that the quantity of sperm and the volume of the sperm sample could be modified in order to have provided the most appropriate sperm sample depending on how the sample would be used – i.e., depending on the amount of sperm present in the original sample, whether the samples would be frozen prior to use, the number of samples to be used for insemination, and the type of insemination technique. Accordingly, to have generated sorted sperm samples containing less than 5 or 25 million sperm or to have generated sorted sperm samples in a volume of .2 or 1 ml would have been obvious to one of ordinary skill in the art because the ordinary artisan would have recognized that the quantity of sperm and the volume of sample should be varied depending on how the sperm sample was to be further processed and / or used.

RESPONSE TO ARGUMENTS:

Applicants state that the preceding arguments are equally applicable to the rejection over Seidel, Wilhelm and Rath, wherein Seidel is cited for using bovine sperm. However, it is noted that the teachings of Seidel are not identical to the teachings of Rens and thereby it is important to emphasize several distinct teachings of the Seidel reference. First, the teachings of Seidel are not in fact limited to "using bovine sperm." Rather, Seidel teaches sorting methods using equine sperm. Secondly, Seidel does teach that using an extender as the collection fluid accomplishes the objective of reducing stress to the sorted sperm. Seidel also acknowledges the conventionality of using an extender as a collection fluid. In particular, Seidel teaches that "it has been known to place an initial collector fluid (17) in the bottom of the container to collect the cells so that they do not hit the bottom of the container" (column 10). Seidel further states that the collector fluid "may serve to minimize chemical stresses upon the cells. In one regard, since it may be important to provide a nutrient to the cells both before and after sorting, the collector fluid (17) may be selected so as to provide a coordinated level of nutrient so that the levels are balanced both before and after sorting" (column 10). The reference teaches that an egg yolk solution may be used as the collection fluid and that the collection fluid may be chosen so that it is similar to the starting fluid environment **or any other fluid environment used in the method** (column 11). Thereby, it is maintained that it would have been obvious to one of ordinary skill in the art and well within the skill of the art to have used an alternative extender as the

Art Unit: 1634

collection fluid, such as the SMEY solution taught by Wilhelm, because this would have provided an effective means for collecting the sorted equine sperm.

Thirdly, the teachings of Seidel emphasize the obviousness and predictability of varying the quantity of egg yolk through routine experimentation. As set forth by Seidel, the levels of egg yolk may be varied "as those skilled in the art readily understand" (column 11).

Further, with respect to claims 51 and 143, Seidel does teach operating the flow cytometer at pressures of about 50 lbs per square inch (column 7).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach

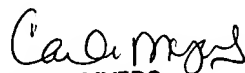
Art Unit: 1634

the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
April 4, 2005


CARLA J. MYERS
PRIMARY EXAMINER